

REMARKS / ARGUMENTS

This letter is responsive to the Office Action mailed April 1, 2005.

The examiner has rejected claims 9 through 14 under 35 U.S.C. 112. The examiner has raised questions concerning the definition of the word "thread". In order to meet the examiner's point, claim 1 has been amended to indicate that the body portion has an external thread including three component parts, that is, a lead thread portion, an intermediate thread portion and a distal thread portion. With this change, then there is no longer the use of the plural term "threads", and appropriate antecedent follows in all other claims. For instance, in claim 9, the claim refers to the lead thread portion and the words "a thread having" have been removed so that the lead thread portion is said to comprise at least three revolutions. Similarly, in claims 10, 11 and 12 the definition of "crest", "root", "crest line" and "root line" respectively, all relate back to the "thread" as defined in claim 1. With these amendments, it is believed that this fully responds to the examiner's position and that the language is now clear and consistent with the drawings and description as originally filed.

The examiner has indicated that there is certain allowable subject matter. Accordingly, in view of the examiner's indication that claims 12 through 14 would include allowable subject matter, a new claim 15 is presented herewith. Claim 15 includes all of the elements of former claims 12, 11, 10, 9, 5, 2 and 1, but includes the amendments made in respect of the 35 U.S.C. 112 objection dealt with above. Thus, it is believed that new claim 15 is an allowable claim. Claim 13 has been amended to depend from newly presented claim 15, thus, claim 13 as amended in this response and claim 14 should now be in condition for allowance.

As the examiner has indicated that claim 12 is directed to allowable subject matter, applicant has reconsidered the subject matter. Applicant now presents new claim 16 which is a combination of former claims 1, 2 and 12. This combination of claims provides all of the antecedent basis required to specifically claim the subject matter of this combination of claims. It is respectfully submitted that the limitations of former claim 12, that is defining the relationship between the root distance and the

cutting distance clearly distinguishes the insert of the present application from any of the art referred to by the examiner. Thus, for the reasons as set out above and below, and based in part on the examiner's indication of allowable subject matter, it is considered that claim 16 is also in condition for allowance. Claims 17, 18, 19 and 20 are dependent upon claim 16, but correspond to originally presented claims 5, 6, 13 and 14 respectively. Accordingly, all of claims 17, 18, 19 and 20 should also be in condition for allowance.

35 U.S.C. 102

The examiner has rejected claims 1 through 6 as being anticipated by Grafelmann 4,863,383. It is respectfully submitted there is no fair basis for the examiner's rejection in this regard and the rejection should be withdrawn.

It is respectfully submitted that in order for a reference to be used as a rejection under 35 U.S.C. 102(b), the disclosure in that asserted anticipatory reference must provide an enabling disclosure of the desired subject matter. In this regard, the examiner's attention is directed to MPEP 2121.01 and in particular, *In re Hoeksema* 399 f. 2d, 269. As pointed out in the MPEP, the mere naming or description of the subject matter is insufficient if it cannot be produced without undue experimentation.

Grafelmann is not in any sense directed to the present invention. Grafelmann describes a self-tapping, screw-in bone implant. The description of Grafelmann describes in detail a particular configuration of screw threads. In particular, Grafelmann teaches a screw thread with a particular profile. The depth of the thread from crest to root decreases from the proximal portion of the implant to the distal portion such that a zero depth of the screw threads is reached at a particular point. Grafelmann also discusses an internal thread for including a post or healing cap and the like. Grafelmann also discloses a self-tapping aspect indicating that his screw threads (sic) have sharp edges. However, Grafelmann is absolutely void of any description as to how a bore is formed in the jaw bone. Grafelmann does not indicate expressly that his device creates a bore as with the current application, but contains several references to inserting the implant into a bore.

It is believed that the examiner's analysis arises from an exercise of reverse engineering based on the present applicant's disclosure, something which is clearly not permitted. By way of example, the examiner indicates that Grafelmann comprises "at least one cutting edge 8". Applicant has carefully reviewed the disclosure of Grafelmann. The description of Grafelmann does not refer at any place to the numeral 8. In figure 1, the numeral 8 appears to refer to a straight line which extends vertically upwardly, that is, longitudinally, of the implant. By comparison, in figure 3, the numeral 8 is indicated by means of an arrow as showing generally something at a very rounded generally hemispherical, or at least semi-circular, profiled tip, of the implant. Thus, there is no depiction of what the structure 8 is, nor is there any explanation of what the cutting edge is which is referred to in the paragraph commencing at line 37. In this regard, Grafelmann states only that to facilitate self-tapping, there are certain indentations formed in each convolution of the thread. There is no explanation in Grafelmann how the indentations facilitate self-tapping. Grafelmann then includes the rather curious statement that "for the same purpose the shank is formed with notches 6". No information is given as to the profile of the notch, only the suggestion that there is a sharp edge. While the edge is described as being sharp, there is no indication that that edge in fact does any cutting. Grafelmann indicates that there is a surface, not numbered either in the description or in the drawings, which "faces in the sense in which the implant is rotated". It is respectfully submitted that there is no clear explanation of what the structure is to which the numerals 6 and 8 have been attached in figure 1. From a single view, it is impossible to determine where the face is, nor the shape of the face referred to by Grafelmann.

The fact that Grafelmann is not an enabling reference is further made clear by reference to various other lines in the Grafelmann drawings which are not explained. With reference to figure 1, there is a chain dotted line running through the crest of the threads of Grafelmann. It is possible that the line is used to show that the line running through the crest is parallel to the axis of the implant or to merely show that the Grafelmann implant is substantially cylindrical as stated in column 2, lines 3 through 11.

Further, Grafelmann in figure 3, shows a similar chain dotted line which extends for most of its length through the tip of the thread parallel to the axis of the implant. However, at the lower portion, the chain dotted line shows a hemispherical or at least semi-circular shape which is tangent to the lowermost curve at the tip of the implant. There is no explicit indication in Grafelmann as to what the chain dotted line is, particularly in the portion where it is shown in a smooth curve.

When there is some doubt as to whether a reference is enabling, it is respectfully submitted that one must try to read what is said in the reference to determine if there is any secondary information within the reference itself which might support the examiner's position. It is respectfully submitted, that all of the disclosure of Grafelmann appears directed to a structure for use in a bore which already exists. Such a bore would be as outlined in the chain dotted line illustrated in figure 3.

Turning to the summary of invention commencing at column 1, line 38, it is said to be an object of the Grafelmann invention to provide "an implant which will contact the bone around the bore (emphasis added), on a larger surface area and reliably to close the free annular space between the bore defining bone surface and the implant". If the Grafelmann device was a self-boring device, then there would have to be something in Grafelmann that extends radially outwardly beyond the envelope to create anything that could be remotely called a free annular space. There is no such structure illustrated in the drawings and the disclosure is absent any description of how such a bore could be created. Similarly, at column 1, line 52 and following, Grafelmann discusses contact between the implement particularly in the region in which the implant contacts the gingival in the upper portion of the bore which receives the implant.

At column 2, line 7, Grafelmann suggests that his entire implant is like a geometric cylinder, including the thread outside diameter. At column 4, commencing at line 31, Grafelmann indicates that because of certain dimensioning of his post, it is possible to use only one caliber shaft drill which relates to the outer implant diameter and the conical inside shank which results in an immediate and tight bore contact. It is respectfully submitted there would be no immediate and tight bore contact in this sense unless there was first a bore.

All of the above is recited in support of applicant's intention that Grafelmann is utterly insufficient as a non-enabling disclosure of the structure claimed in the present claims. This is in part because it is submitted the Grafelmann invention has nothing whatever to do with a self-boring implant, only a self-tapping implant. In certain circumstances, when a reference is alleged to be deficient, the reference may nonetheless be utilized if secondary evidence would show public possession of the invention. This is clearly not the case here, as all secondary evidence referred to by the examiner at any time during the prosecution of this application refers to self-tapping devices to be inserted into a previously drilled bore. Thus, no reliance on any secondary evidence overcomes the deficiencies of Grafelmann.

35 U.S.C. 103

The examiner has rejected claim 7 through 9 in view of Grafelmann and Day. The examiner's rejection is as set out in connection with the 102 rejection, but then continues on to deal with the flute. As stated above, Grafelmann does not disclose any of the issues raised in claims 1 through 6, and thus, no combination of Grafelmann with any other reference would lead to the invention claimed.

Claims 9 through 11 have been rejected on the combination of Grafelmann and Beaty. Again because of the limitations of Grafelmann as set out above, there is nothing in the combination of Grafelmann and Beaty which would otherwise give a self-boring implant.

In view of all of the arguments set out above, applicant continues to press for the allowability of claims 1 through 12. The structure as claimed in claim 1 clearly defines that the tip portion comprises at least one cutting edge for cutting bone to form a bore. No other reference includes at least one cutting edge for cutting bone to form a bore. This is not taught in any of the references and in fact, all of the references teach directly away from this structure. In each case, the references refer to a bore and thus require an initial boring operation prior to any attempt to install the implant. Thus, none of the prior references deal with the advantage disclosed in the current invention.

In view of all of the foregoing, it is respectfully submitted that in addition, claims 1 through 12 are in condition for allowance.

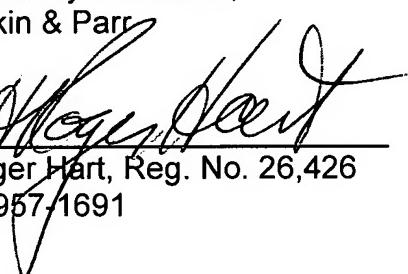
Appln. No. 10/086,860
Amdt. dated June 20, 2005
Reply to Office Action of April 1, 2005

It is considered that this is fully responsive to the examiner's office action and presents the claims in allowable form including the subject matter indicated by the examiner as allowable subject matter.

In view of the number of total claims cancelled and the additional claims added and in view of the number of independent claims cancelled and added, it is believed that no additional fees are required either for independent claims or in respect of the total number of claims.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
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